

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,
CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
IOWA, LOUISIANA, MASSACHUSETTS,
MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND,
TENNESSEE, TEXAS, VERMONT,
VIRGINIA, WASHINGTON, WISCONSIN,
and the DISTRICT OF COLUMBIA
ex rel. URI BASSAN,

Plaintiffs,

v.

OMNICARE, INC.,

Defendant.

Case No. 15-CV-4179 (CM)

UNITED STATES OF AMERICA,

Plaintiff,

v.

OMNICARE, INC. and CVS HEALTH CORP.,

Defendants.

**MEMORANDUM IN SUPPORT OF OMNICARE'S MOTION TO DISMISS
RELATOR'S COMPLAINT**

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Relator Uri Bassan, a former Omnicare employee, claims to have discovered a fraud that Omnicare allegedly perpetrated on twenty-nine state governments over a fourteen-year period.¹ The Complaint's wide-ranging allegations lack any detail, beyond conclusory assertions, that could plausibly support any aspect of these sweeping fraud claims. Bassan alleges that Omnicare pharmacies defrauded the states' Medicaid programs by requesting payment for drugs dispensed to residents of long-term-care facilities without valid prescriptions. But he does not plead facts suggesting that even a single such prescription claim was *ever* submitted to *any* of the states for payment. Even putting aside his failure to allege the central required element of a false "claim," Bassan also offers nothing but conclusory speculation to allege the other elements of a False Claims Act violation:

Falsity: Bassan asserts that the federal Medicaid law incorporates state-law guidance, which he claims uniformly limits the number of prescription refills pharmacies can provide to residents of long-term-care facilities. But Bassan alleges no support for the idea that the federal Medicaid law incorporates this state-law guidance, and makes no specific allegations regarding any guidance issued by any of the twenty-nine states for which he sues. As a matter of fact, directly contrary to Bassan's claims, at least twenty-one of the states explicitly permit the dispensing practice Bassan claims was fraudulent.

Intent: Bassan asserts that Omnicare has been "knowingly" defrauding the states since 2006, but he bases his claim of scienter on conversations in April and May 2015, when he alleges he raised his concerns with Omnicare employees concerning the pharmacy in New

¹ With the Government's December 2019 intervention to prosecute the federal claim that Bassan also brought, Bassan's Complaint is now operative as to the state claims only, see *infra*, Part I. (As set forth in Omnicare's separate motion to dismiss, the federal claim brought by the Government also should be dismissed. See Motion to Dismiss Gov't Complaint.)

Mexico where he worked. Bassan’s own account of those discussions, however, reveals diligent and expeditious responses from Omnicare managers. Regardless, a handful of discussions regarding a single New Mexico pharmacy in 2015 cannot establish a knowing, twenty-nine-state fraud since 2006.

Materiality: False Claims Act plaintiffs must allege facts sufficient to show “materiality,” meaning that the false statement was significant to the government’s decision to pay the claims. Bassan makes no allegation that any of the states for which he sues would have deemed Omnicare’s alleged conduct material.

BACKGROUND²

A. Requirements for Dispensing Prescriptions to Residents of Long-Term-Care Facilities Vary Widely.

Bassan alleges that Omnicare is a long-term-care pharmacy that operates “approximately 146 pharmacies” serving long-term-care facilities “located in at least forty-seven states.” Dkt. No. 16 (Complaint) ¶¶ 10–11 (“Compl.”). Over the years, Omnicare has dispensed prescriptions “to millions of elderly and disabled individuals who reside in hundreds of facilities throughout the count[r]y.” *Id.* ¶ 11. Like the Government’s Complaint, Bassan’s classifies the array of long-term-care facilities into two neat categories: Skilled Nursing Facilities (“SNFs”), which generally make “nursing services . . . available 24 hours a day” and place “the care of every SNF patient . . . under the supervision of a physician,” *id.* ¶ 29, and non-SNFs (which Bassan calls Assisted Living Facilities or “ALFs”), *id.* ¶ 30. As even the Government admits, however, the array of long-term-care facilities Omnicare serves provide different types of services to patients with varying medical conditions. *See* Dkt. No. 17 (Complaint-in-Intervention) ¶¶ 73, 75, 77, 78

² Omnicare’s recitation of the Complaint’s allegations is not an agreement that they are true.

(“Gov’t Compl.”); Motion to Dismiss Gov’t Complaint at 2–3. Bassan’s distinction between SNFs and ALFs thus does not match the law or industry reality. Even he hedges that distinction, for example, stating that “*most* residents of ALFs, like the many millions of other Americans who do not reside in SNFs, receive valid prescriptions from their physicians directly and submit them to a local licensed pharmacy.” Compl. ¶ 30 (emphasis added).

Bassan brings this case on behalf of the Medicaid programs of twenty-nine states, based on his assertion that the federal Medicaid law incorporates a uniform set of rules from the laws of each of the states. But Bassan cites to no federal guidance regarding the relevant prescription requirements under Medicaid. He suggests that 42 U.S.C. § 1396d(a)(12) incorporates into Medicaid a host of nuanced, state-specific guidelines regarding prescription documentation, *see id.* ¶¶ 103, 105, but that provision merely states that Medicaid may cover “prescribed drugs,” with no definition of the term or reference to any state law.

Nor is Bassan correct to allege that the laws of the twenty-nine states for which he sues are uniform or that they forbid pharmacies from refilling prescriptions for residents of long-term-care facilities based upon a medication order that does not specify the number of refills that are authorized. Bassan agrees that prescriptions to residents of SNFs may be dispensed based upon “chart orders,” *see id.* ¶ 29, which are, as the Government alleges, prescriptions that “do not typically specify the total quantity prescribed or the number of refills authorized,” Gov’t Compl. ¶ 99. But Bassan purports to draw a hard line between SNFs (where such practices are permitted) and all other facilities (where he claims they are not). *See, e.g.,* Compl. ¶¶ 29–30, 112. In fact, 21 of the 29 states for which Bassan sues explicitly *permit* the conduct Bassan accuses Omnicare of engaging in, including Bassan’s home state of New Mexico. *See* N.M. Admin. Code § 7.8.2.35 (declaring, for assisted-living facilities, that “[n]o medications . . . shall

be started, changed or discontinued by the facility without an order from the physician, physician assistant or nurse practitioner and with entry into the resident’s record”). Many states do not draw any line between SNFs and other long-term-care facilities for purposes of these types of medication orders. *See, e.g.*, Minn. Stat. § 151.01(16b) (allowing use of “chart order” prescription—which need not include the quantity prescribed—“during the patient’s stay in a hospital *or long-term care facility*” (emphasis added)); N.J. Code Ann. § 13:39-9 (“‘Medication order’ means a written request for medication originated by a practitioner and intended for patient use in the *health care facility*.” (emphasis added)). And the state laws that permit the use of medication orders without a quantity or refill limit apply not just to SNFs but to a range of facilities, including “assisted living center[s],” “assisted living program[s],” “extended care facilit[ies],” “facilit[ies],” “long-term-care facilit[ies],” “health care institution[s],” “health facilit[ies],” “health care facility[ies],” “institutional facility[ies],” “institution[s],” “licensed medical care facilit[ies],” “medical facilit[ies],” and “rest homes with nursing supervision.” Ex. 1 (State-Law Chart). These terms, moreover, are defined in different ways (if at all) across the states. *See id.*

B. Bassan’s Theory of Liability.

Bassan alleges that Omnicare knowingly evaded these state-law requirements from January 1, 2006 onward. But he bases these allegations on unfounded speculation, which is largely discredited by his own allegations that Omnicare took steps to follow state law.

Bassan admits that Omnicare’s dispensing process utilizes a number of computer steps to automate the refilling of patients’ prescriptions. *See* Compl. ¶ 37. When Omnicare receives a prescription, its staff are tasked with “enter[ing] information about those prescriptions,” and “are

prompted by Omnicare’s pharmacy dispensing system to enter (among other elements of the prescription) the specific total *quantity* of the legend drug being prescribed.” *Id.* ¶ 48.

Bassan alleges that Omnicare also dispensed via an automated “cycle fill” process by which prescriptions requiring refills for multiple residents of a particular long-term-care facility are filled for delivery all at one time. *See id.* ¶¶ 37, 41, 45. Under this process, Omnicare would provide the relevant “administrator[]” at the long-term-care facility an authorization form to be reviewed and completed “on a regularly scheduled basis.” *Id.* ¶ 44. This form prompted the facility’s “Director of Nurses” or that person’s designee to review all medications scheduled for refilling and note which medications should not be filled at that time. Dkt. No. 16-3 (Ex. C to Compl.). Despite this, Bassan alleges, the cycle-fill computer process did not independently alert Omnicare pharmacy staff when prescriptions destined for ALFs were out of refills. *See* Compl. ¶ 53.

Nowhere does Bassan allege that *any* Omnicare employee was *ever* instructed to dispense prescriptions that were invalid or to otherwise disregard any of the processes that had been set up to prevent such dispenses. Nor does he allege that any patient received a prescription that was not actually used or needed. Instead, Bassan acknowledges that cycle-fill was a dispensing process made available to both SNFs and ALFs, *see id.* ¶ 40, agrees that use of prescriptions without limitations on refills is entirely proper for SNFs, *see id.* ¶ 110, and merely faults Omnicare for not realizing sooner that the automated process was allowing prescriptions for ALF residents to be filled via the cycle fill process after refills were exhausted. *See id.* ¶ 58.

Bassan claims he discovered this programming anomaly during a 2015 audit of one of the facilities served by his New Mexico pharmacy, when Bassan was unable to locate records for certain prescriptions. *See id.* ¶ 60. He then conducted some mock experiments with the

dispensing system, and concluded that Omnicare’s dispensing system was (A) correctly blocking the refill of prescriptions when “the total quantity prescribed had been dispensed,” but (B) not imposing the same block when Bassan created a mock refill of the prescription using the cycle-fill process. *Id.* ¶ 62. From this, Bassan infers “that Omnicare’s cycle fill system was intentionally designed to allow” dispenses to occur “without prescriber authorizations.” *Id.* ¶ 61.

Bassan claims that Omnicare knew that this was occurring because he brought the alleged flaw to the attention of a member of Omnicare’s Information Solutions team and a Regional Compliance Officer, all in late-April 2015. *See id.* ¶¶ 39, 63. Although Bassan admits that Omnicare officials responded quickly on May 1, 2015, and that they “believed [they] had discovered a supposed ‘flaw’ in Omnicare’s computer code,” *id.* ¶ 63, Bassan infers something more nefarious from the fact that he did not receive a further response until May 4, 2015, at which point the person with whom he corresponded believed that there was no flaw because the process was entirely proper for residents of SNFs, *see id.* ¶ 65. Bassan did not clarify his concerns with the process as applied to residents of ALFs, instead inferring that Omnicare must have been trying to “mislead[]” him. *See id.* ¶¶ 65–66. Bassan next demanded that Omnicare provide him “a report that would identify the ‘problematic’ prescriptions,” *id.* ¶ 67, but when he received a May 15, 2015 report that was “different than what he had requested,” Bassan gave up and assumed Omnicare was trying to “bur[y]” him, *id.* ¶ 68.

From these events, Bassan infers that Omnicare has been intentionally dispensing prescriptions to residents of ALFs when those prescriptions were out of authorized refills. *See id.* ¶ 108. Bassan also alleges that these dispensing practices extended to certain controlled substances, although he admits that he “does not currently have a specific example of a controlled substance being dispensed without a valid prescription based on Omnicare’s

automated cycle fill system because his New Mexico pharmacy has chosen not to use cycle fill when filling prescriptions for controlled substances.” *Id.* ¶ 145. Bassan merely “believes” that such dispenses have happened at other Omnicare pharmacies, of which he admittedly has no knowledge. *Id.* Further, despite Bassan’s admission that he was unaware of his allegations until the middle of 2015, Bassan also assumes that the dispensing practices have been happening since January 1, 2006. *See id.* ¶¶ 113–119.

PROCEDURAL HISTORY

On June 1, 2015, Bassan filed this case, alleging violations of the federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729–3733, and the corresponding state laws of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin (collectively, the “State FCAs”). Compl. ¶ 1. The case remained under seal for over four years, while the Government conducted its investigation. On December 17, 2019, the federal Government filed its Complaint-in-Intervention and took over the litigation of Bassan’s federal FCA claims. Gov’t Compl. All of the States (save Indiana) have declined to intervene in this action. *See* Dkt. No. 22 (Declination Notice) (filed on behalf of all states, save Indiana and the District of Columbia); Dkt. No. 64 (D.C. Declination Notice).³ Indiana has not filed anything at all and, with any deadline for intervention and the March 12, 2020 deadline for the filing of amended complaints having

³ Maryland further requested that the claims under Maryland law be dismissed upon its declination, as required by the Maryland False Health Claims Act, *see* Md. Code Ann., Health Gen. § 2-604(a)(7). Dkt. No. 22 (Declination Notice) at 2. The Court granted Maryland’s request and dismissed the Maryland FCA claim. *See* Dkt. No. 21 (Dec. 13, 2019 Order) at 2.

expired, should be deemed to have declined as well.⁴ The Court should now dismiss all of Bassan’s State FCA claims.

ARGUMENT

I. BASSAN’S FEDERAL FCA CLAIMS SHOULD BE DISMISSED BECAUSE THE GOVERNMENT’S COMPLAINT SUPERSEDED THEM

The federal FCA permits a relator to proceed only “on behalf of the Government,” *United States ex rel. Barajas v. Northrop Corp.*, 147 F.3d 905, 910 (9th Cir. 1998), as a recipient of “a partial assignment of the Government’s damages claim.” *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 765–66 (2000). Bassan has “no separate free-standing FCA cause of action” apart from the Government’s claim. *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 4287572, at *4 (D. Mass. Dec. 6, 2007). Thus, Bassan’s federal FCA claims were superseded by the Government’s Complaint-in-Intervention and Bassan lacks “standing” to pursue them. *United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 648 (S.D.N.Y. 2011).⁵

⁴ Should Indiana’s silence not be deemed a declination, Bassan does not have the right to prosecute the action on behalf of Indiana because Indiana must affirmatively elect not to intervene in an action before any relator may proceed with a *qui tam* suit. See Ind. Code Ann. § 5-11-5.7-5(e) (A relator has “the right to prosecute the action” on the State’s behalf **only** “[i]f the attorney general or the inspector general elects not to intervene in the action.”); see also Ind. Code Ann. § 5-11-5.5-4(e)(2) (state may “elect not to proceed with the action, in which case the person who initially filed the complaint may proceed with the action”); *United States ex rel. Rahimi v. Zyduz Pharms.*, 2017 WL 1503986, at *14 (D.N.J. Apr. 26, 2017) (interpreting Indiana’s FCA to “require[] either the jurisdiction or an official thereof to notify the Court of that jurisdiction’s decision to decline intervention”), *reconsidered in part on other grounds*, 2018 WL 515943 (D.N.J. Jan. 23, 2018); see also *United States ex rel. Simpson v. Bayer Corp.*, 2014 WL 1418293, at *11 (D.N.J. Apr. 11, 2014) (same); *United States v. Select Specialty Hosp.-Wilmington, Inc.*, 2018 WL 1568874, at *7 (D. Del. Mar. 30, 2018) (same under similar provision of Delaware law).

⁵ Bassan’s counsel has indicated to Omnicare’s counsel that Bassan agrees with this view.

II. BASSAN DOES NOT STATE A CLAIM UNDER THE STATE FCAS

Bassan brings claims under State FCAs that largely “parallel” the federal provisions, *United States ex rel. Kester v. Novartis Pharms.*, 43 F. Supp. 3d 332, 339 (S.D.N.Y. 2014), and therefore follow federal case law in interpreting them, *see, e.g., New York v. Amgen, Inc.*, 652 F.3d 103, 109 (1st Cir. 2011) (interpreting State FCAs of California, Georgia, Illinois, Indiana, Massachusetts, New Mexico, and New York to be consistent with the federal FCA). To plead his claims, Bassan must allege that: “(1) there was a false or fraudulent claim, (2) the defendant knew it was false or fraudulent, (3) the defendant presented the claim, or caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury.” *United States ex rel. Kester v. Novartis Pharms.*, 23 F. Supp. 3d 242, 252 (S.D.N.Y. 2014). Bassan also must plead that the alleged falsity was “material to the Government’s payment decision.” *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). And he must plead his claim with particularity under Federal Rule of Civil Procedure 9(b). *See United States ex rel. Chorchos v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017).

Bassan’s complaint should be dismissed for multiple reasons. *First*, he does not plead his claims with the particularity demanded by Rule 9(b) and the FCA. *Second*, Bassan does not sufficiently allege that the prescription claims about which he sues were actually “false.” *Third*, Bassan does not sufficiently allege that Omnicare acted “knowingly.” *Fourth*, Bassan does not plead facts showing that the alleged falsity was “material” to any state’s decision whether to pay the claim.

A. Bassan Fails to Plead the Submission of Particular False Claims.

Because the State FCAs all require the existence of false “claims,” Bassan must “plead with particularity that false claims were actually submitted to the government.” *Kester*, 23 F. Supp. 3d at 252. He “cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted.” *Id.* at 253 (internal quotation marks omitted); *see also Chorchos*, 865 F.3d at 86 (stating that the “standard ‘must not be mistaken for license to base claims of fraud on speculation and conclusory allegations’” (quoting *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990))). Rather, Bassan “must plead both the particular details of a fraudulent scheme and ‘details that *identify particular false claims for payment* that were submitted to the government.’” *Kester*, 23 F. Supp. 3d at 255 (quoting *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004)).

Of particular significance here, when a relator brings State-FCA claims, “[c]ourts have required that relators ‘allege some specificity ***with respect to each asserted state*** and cannot rely upon generalized pleadings.’” *United States v. Lab. Corp. of Am. Holdings*, 2015 WL 7292774, at *6 (S.D.N.Y. Nov. 17, 2015) (emphasis added) (quoting *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 357 (D. Mass. 2011)); *see also United States ex rel. Nargol v. Depuy Orthopaedics, Inc.*, 865 F.3d 29, 42 (1st Cir. 2017) (dismissing State-FCA claims that included only “conclusory allegations that state and municipal analogues to the FCA were violated when claims for reimbursement were submitted for covered patients in a handful of states and municipalities”); *United States ex rel. Kroening v. Forest Pharms.*, 155 F. Supp. 3d 882, 896–97 (E.D. Wis. 2016) (“[C]laims under companion state false claims statutes must *each* be supported with details sufficient to satisfy the particularity required under Rule 9(b).” (emphasis added)). Bassan fails to do so for each of his State FCA claims.

Bassan’s allegations do not suggest that a single allegedly false claim was submitted to the Medicaid program of any of the twenty-nine states whose laws he invokes. With the exception of New Mexico, Bassan does not plead **anything** about those states, except for vague and conclusory assertions, repeated for each state, that “[b]y virtue of the acts described above, Defendant Omnicare knowingly submitted . . . false or fraudulent claims.” Compl. ¶¶ 154, 159, 164, 169, 174, 179, 184, 189, 194, 199, 204, 209, 214, 219, 224, 229, 234, 239, 244, 249, 254, 259, 264, 269, 274, 279, 284, 289, 294, 299. Such assertions “do not even come close to satisfying the pleading requirements.” *United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 270 (D. Mass. 2015) (dismissing 25 state-FCA claims that included similar conclusory allegations, where, for 18 of the states, the complaint had “no allegations . . . of fraudulent conduct or false claims beyond the conclusory allegations” and, for the other seven, it had “barely any mention of fraudulent activity”), *aff’d*, 844 F.3d 26 (1st Cir. 2016).

Bassan’s allegations regarding events occurring in New Mexico do not provide a basis for a claim even under New Mexico law. Bassan identifies three claims for payment by Omnicare, but he alleges that each was a **federal** claim submitted to **Medicare**. See Compl. ¶¶ 121–140, Dkt. Nos. 16-5, 16-6, 16-7 (Exs. E, F, G to Compl.). Bassan therefore alleges nothing to suggest that any claim for payment was submitted to the State of New Mexico or its Medicaid program. And “it is insufficient for purposes of Rule 9(b) to merely imply state FCA claims based on alleged federal FCA claims” or to “infer, based on allegations that [Defendant’s] practices violated the federal FCA” with respect to “beneficiaries of *federally* funded programs, that false claims were also submitted to the Medicaid programs of each of the . . . states.” *United States ex rel. Chin v. CVS Pharmacy, Inc.*, 2017 WL 4174416, at *8 (C.D. Cal. Aug. 15, 2017); see also *United States ex rel. Mooney v. Americare, Inc.*, 2013 WL 1346022, at *7 n.6 (E.D.N.Y.

Apr. 3, 2013) (“Because none of the twelve exemplars represent claims made to Medicaid, the exemplars do not provide defendants with notice of any Medicaid claims. Thus, as stated above, the scheme is insufficiently pled as it relates to Medicaid.”).

Finally, although there are circumstances under which an FCA complaint need not include “details of actual bills or invoices submitted to the government,” that exception applies only where the complaint’s allegations “lead to a strong inference that specific claims were indeed submitted *and* that information about the details of the claims submitted are peculiarly within the opposing party’s knowledge.” *Chorches*, 865 F.3d at 93 (emphasis added). Those “who *can* identify examples of actual claims *must* do so at the pleading stage.” *Id.* at 86. Bassan, as an Omnicare employee making allegations based on his alleged personal experiences, was in a position to identify such examples, if they exist, and *Chorches* required him to. *See United States ex rel. Gelbman v. City of New York*, 790 F. App’x 244, 248 (2d Cir. 2019) (rejecting relator’s attempt to evade pleading requirements where relator alleged Medicaid fraud in New York while working “as an Information Specialist working on Medicaid reimbursement at [the New York Department of Health], the agency responsible for submitting Medicaid claims to the federal government”). Bassan’s State FCA claims should each be dismissed for failure to comply with Rule 9(b).

B. Bassan Does Not Sufficiently Allege That Omnicare Submitted Claims for Payment That Were “False or Fraudulent.”

Even if Bassan had met the Rule 9(b) standard, his claims would still be invalid because he does not allege facts showing that Omnicare submitted claims for payment that were “false.” *See Kester*, 23 F. Supp. 3d at 252. It is axiomatic that “[c]laims are not ‘false’ under the FCA unless they are furnished in violation of some controlling rule, regulation or standard.” *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006); *see also United States ex rel.*

Glass v. Medtronic, Inc., 957 F.2d 605, 608 (8th Cir. 1992) (affirming grant of summary judgment after concluding that the defendant’s actions were “proper” under the applicable Medicare provision and therefore “not false or fraudulent”). Bassan, however, makes no allegations to support his theory of falsity.

1. Bassan’s Nationwide Theory of Falsity Is Baseless.

Bassan’s falsity allegations focus on Medicare, *see* Compl. ¶¶ 70–99, but the Government’s Complaint is now the operative pleading for those claims. As to his State FCA claims, which relate to Medicaid, Bassan alludes to 42 U.S.C. § 1396d(a)(12), and suggests that it limits Medicaid coverage in all states to incorporate all aspects of each individual state’s prescription requirements. *See id.* ¶¶ 103, 105. But § 1396d(a)(12) merely states that Medicaid may cover “prescribed drugs,” with no definition of the term or reference to the nuances of state law. Bassan’s claim under each State FCA is premised on the idea that the Medicaid statute incorporates each state’s requirements related to prescriptions and medication orders. Bassan alleges no legal grounding for this theory of falsity. For this reason, each of his State FCA claims should be dismissed.

2. Bassan’s State-Law Theory of Falsity Is Baseless.

Even assuming for argument’s sake that Bassan were correct that a violation of state prescription requirements automatically makes a claim to Medicaid “false,” each of his State FCA claims would still fail because he makes no allegation regarding the content of any of the 29 states’ laws concerning prescription documentation. Bassan agrees that prescriptions to residents of SNFs may be dispensed based upon “chart order[]” prescriptions that do not include the total quantity prescribed or number of authorized refills, and that such chart orders may be reused indefinitely. *See* Compl. ¶ 29. Bassan asserts that “ALFs cannot use chart orders,” *id.* ¶

30, but he does not cite any authority for that proposition. The core of Bassan’s theory—that Omnicare was not permitted to use such prescriptions when dispensing to residents of ALFs—is wholly unsupported.

Bassan’s pleading failure is unsurprising, because he is flatly wrong about the law. No fewer than 21 of the 29 states for which Bassan sues had laws that *explicitly permit* use of chart orders at long-term-care facilities other than SNFs. *See, e.g.*, Minn. Stat. § 151.01(16b) (allowing use of “chart order” prescription—which need not include the quantity prescribed—“during the patient’s stay in a hospital *or long-term care facility*” (emphasis added)); Wash. Code Rev. §§ 18.64.011, 18.64.550 (same for long-term-care facilities, including nursing homes, assisted living facilities, and adult family homes). These states are: Colorado, Connecticut, Delaware, the District of Columbia, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Vermont, Virginia, and Washington. Ex. 1 (State-Law Chart).⁶

These states permit the use of medication orders that do not specify the quantity prescribed or number of refills in a range of facilities. Some states describe the facilities in which such orders are permitted using terms that, on their face, include the “ALF” facilities that Bassan claims are excluded. *See* Colo. Rev. Stat. § 12-42.5-102(24)(b) (“long-term care facility”); Minn. Stat. § 151.01(16b) (“long-term care facility”); Okla. Stat. Ann. tit. 59, § 353.1 (“assisted living center”); Va. Code Ann. § 54.1-3408.01(A) (“long-term-care facility”); Wash.

⁶ Exhibit 1 is a chart of state laws, which is not intended to be comprehensive, and includes only states for which claims have been brought by Bassan or which are otherwise clearly associated with the claims the Government has identified in its Complaint. In addition to the statutory and regulatory provisions discussed in the chart, pharmacy dispensing is subject to guidance by, among other things, state boards of pharmacy and other sub-regulatory guidance, payer guidelines, and standards of pharmacy practice.

Code Rev. § 18.64.550 (“long-term care facility”). Other states use terms that sweep even more broadly. *See* Conn. Agencies Regs. § 19-13-D8v(b)(5) (“rest homes with nursing supervision”); Ind. Code Ann. § 25-26-13-2 (“health care institution”); Iowa Admin. Code r. 657-23.2(155A) (“facility”); La. Stat. Ann. § 37:1164 (“institutional facility”); 105 Code Mass. Regs. § 700.001 (“health facility”); Mich. Comp. Laws Ann. § 333.17708 (“health facility”); Mont. Admin. R. 24.174.831 (“facility”); Nev. Admin. Code 639.442 (“medical facility”); N.J. Stat. Ann. § 13:39-9 (“health care facility”); N.Y. Comp. Codes R. & Regs. Tit. 8, § 29.7 (“health care facility”); 21 N.C. Admin. Code § 46.1414 (“health care facility”); Vt. Code Regs. 04-030-230 §§ 11.2(a), 11.26 (“institutional facility”); 22-B D.C. Mun. Regs. §§ 1999, 1999.1 (“institutional facility”). These terms, moreover, are defined in myriad ways across the states, but all of them underscore that “ALFs” are covered. *See* Ex. 1 (State-Law Chart). In Delaware, Indiana, and New York, the term used to describe which facilities may utilize such prescriptions is wholly undefined, although closely related terms are defined in ways that encompass “ALFs.” *See id.* Finally, in Illinois, Iowa, Massachusetts, New Jersey, Vermont, and Washington, the definitions refer back to an analysis of each long-term-care facility’s specific licensing status with state agencies. *See id.*

“Claims are not ‘false’ under the FCA unless they are furnished in violation of some controlling rule, regulation or standard.” *Prabhu*, 442 F. Supp. 2d at 1026. (And even if the Court were to interpret any of these state-law requirements differently from Omnicare, the requirements were ambiguous, which would independently foreclose the claim. *E.g., United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (“[I]mprecise statements or differences in interpretation growing out of a disputed legal question are . . . not

false under the FCA.”.) In the absence of a well-pleaded and particularized claim of a violation of law, Bassan’s complaint should be dismissed.

C. Bassan Does Not Sufficiently Allege That Omnicare Acted “Knowingly.”

Bassan also does not plead facts showing that Omnicare “knowingly” submitted the allegedly false claims. 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B). “Knowingly,” under the FCA, is defined to include acting “in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A)(iii). This intent standard is “rigorous” and must be “strict[ly] enforce[d].” *Escobar*, 136 S. Ct. at 2002. “[T]he requisite intent” under the FCA “is the knowing presentation of what is known to be false as opposed to negligence or innocent mistake.” *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001) (internal quotation marks omitted), *abrogated on other grounds by Escobar*, 136 S. Ct. 1989. In FCA cases, the Second Circuit “ha[s] repeatedly required plaintiffs to plead the factual basis which gives rise to a strong inference of fraudulent intent.” *United States ex rel. Tessler v. City of New York*, 712 F. App’x 27, 29 (2d Cir. 2017) (quoting *O’Brien v. Nat’l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)). Bassan fails to do so here.

Bassan admits that Omnicare had systems in place to ensure that prescriptions were dispensed appropriately. *See* Compl. ¶¶ 44–46, 48, 49. He makes no allegation that any Omnicare employee intentionally evaded those systems (or that anyone in management told any employee to do so). In fact, he admits that the Omnicare employees to whom he first raised his concerns in late-April 2015 responded that he had identified a “flaw” in the Omnicare computer system. *Id.* ¶ 63.

The FCA’s “reckless disregard” standard sets a much higher bar: “Recklessness entails conduct that is ‘highly unreasonable and which represents an extreme departure from the

standards of ordinary care.” *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs.*, 318 F. Supp. 3d 680, 694 (S.D.N.Y. 2018) (quoting *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996)). Thus, mere “errors in data collection or recognizing the need for better quality control does not constitute ‘reckless disregard’ within the meaning of the FCA.” *United States ex rel. Kirk v. Schindler Elevator Corp.*, 130 F. Supp. 3d 866, 879 (S.D.N.Y. 2015). Bassan’s allegation that Omnicare’s system was set up in a way that treated ALFs the same as SNFs is not enough because “[t]he mere failure of a system to catch an error does not establish recklessness.” *United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 110 (3d Cir. 2007). Indeed, Bassan admits that Omnicare’s system required each facility’s “Director of Nurses” or that person’s designee to review all medications scheduled for refilling and note which medications should not be filled at that time. Dkt. No. 16-3 (Ex. C to Compl.). At most, Bassan alleges the existence of a system that, in retrospect, was imperfect and susceptible to human error. But “[p]roof of reckless disregard requires much more than errors, even egregious errors.” *United States ex rel. Ervin & Assocs. v. Hamilton*, 298 F. Supp. 2d 91, 101 (D.D.C. 2004).

Nor can intent be inferred from Bassan’s assertions about his communications with other Omnicare personnel. Bassan’s allegations amount to a complaint that Omnicare staff did not respond to his concerns instantaneously in April and May 2015, that they misunderstood his concerns as being related to SNFs instead of ALFs, and that they provided him with a comprehensive report of prescriptions filled (at his request) that did not include the specific information he wanted. *See* Compl. ¶¶ 63–68. The responses catalogued in Bassan’s Complaint reflect employees taking Bassan’s concerns seriously, elevating them, and responding to his demands for more information. That is far from the “‘extreme departure from the standards of ordinary care’” needed to allege recklessness under the FCAs. *Grubea*, 318 F. Supp. 3d at 694

(quoting *Chill*, 101 F.3d at 269). And if those employees questioned Bassan’s concerns, that would be unsurprising as his pharmacy was located in New Mexico, where state law *permitted* Omnicare’s alleged conduct. See N.M. Admin. Code § 7.8.2.35 (declaring, for assisted-living facilities, that “[n]o medications . . . shall be started, changed or discontinued by the facility without an order from the physician, physician assistant or nurse practitioner and with entry into the resident’s record”).

Even if these allegations were somehow enough to state a claim under the New Mexico FCA, the allegations stem from April 2015, at the earliest. Bassan’s claim would still be defective for the almost-ten-year period prior to April 2015 about which he purports to sue because ““there is no fraud by hindsight.”” *United States ex rel. United Union of Roofers, Waterproofers & Allied Workers Local No. 11 v. City of Chicago*, 2014 WL 6306582, at *4 (N.D. Ill. Nov. 12, 2014) (quoting *United States ex rel. Garst v. Lockheed–Martin Corp.*, 328 F.3d 374, 378 (7th Cir. 2003)); see also *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1359 (S.D. Fla. 2015) (where “the last exemplar transaction at issue was initiated in May 2009,” purported evidence of intent from “October 2009” could not suffice; “Relators do not explain how an October email would allow a reasonable jury to conclude that [Defendant] knowingly submitted false claims in May of the same year”), *aff’d as modified*, 857 F.3d 1148 (11th Cir. 2017).

* * *

Bassan’s intent allegations are insufficient to state a claim under any of the State FCAs and his claims should be dismissed for that reason. But even if his New Mexico-focused allegations were sufficient as to allege knowledge with respect to that one pharmacy, they say nothing about any other pharmacy or state, requiring dismissal of all of Bassan’s other State FCA

claims. *See United States ex rel. Jorgenson v. Alan Ritchey, Inc.*, 2007 WL 1287932, at *3 (W.D. Wash. Apr. 27, 2007) (dismissing FCA allegations regarding fraud at company locations other than the one about which the relator asserted insider knowledge because “alleged fraudulent activity at one plant does not constitute an allegation for a different plant”); *accord United States ex rel. Acad. Health Ctr. v. Hyperion Found.*, 2014 WL 3385189, at *33 (S.D. Miss. July 9, 2014).

D. Bassan Does Not Sufficiently Allege That Any False Claim Was “Material” to Any State.

Bassan also fails to allege facts showing that Omnicare’s allegedly false claims were “material to the Government’s payment decision,” *Bishop v. Wells Fargo & Co.*, 870 F.3d 104, 107 (2d Cir. 2017) (per curiam), for any of the twenty-nine states. The “materiality standard is demanding,” and must be pleaded “with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b).” *Escobar*, 136 S. Ct. at 2003, 2004 n.6. “[M]ere non-compliance with a regulation is not enough to give rise to FCA liability.” *United States ex rel. Scharff v. Camelot Counseling*, 2016 WL 5416496, at *8 (S.D.N.Y. Sept. 28, 2016). Rather, “the complaint must present concrete allegations from which the court may draw the reasonable inference that the [alleged falsity] caused the Government to make the reimbursement decision.” *Coyne v. Amgen, Inc.*, 717 F. App’x 26, 29 (2d Cir. 2017); *see also United States ex rel. Raffington v. Bon Secours Health*, 405 F. Supp. 3d 549, 562 (S.D.N.Y. 2019) (inquiry is “what the Government would likely actually do if presented with a claim for payment that was explicitly” defective in the manner alleged to be false). Nor can the complaint get by on “conclusory” recitations of this standard. *United States ex rel. Daugherty v. Tiversa Holding Corp.*, 342 F. Supp. 3d 418, 428–29 (S.D.N.Y. 2018) (dismissing FCA claim where complaint “pleads only in a conclusory fashion that the Government refuses to pay grants due to falsified

methodology” and “general policies . . . that compliance with grant conditions is important to the Government”); *see also Scharff*, 2016 WL 5416494, at *8 (dismissing where complaint contained only a “conclusory assertion” that the regulation was “material”).

Bassan falls far short of this burden. He makes no allegation that the matters about which he sues were important to *any* State’s payment decision. Bassan’s allegations as to materiality are limited to a conclusory recitation of the legal definition of materiality, *see* Compl. ¶ 20, and the unadorned assertion that “Medicaid’s coverage for outpatient drugs excludes medications that are dispensed without a valid prescription,” *id.* ¶ 105.⁷ Merely stating that Medicaid, as a general matter, excludes coverage for drugs dispensed without a valid prescription does not provide any “concrete allegations from which the court may draw the reasonable inference that the [alleged falsity] caused the Government to make the reimbursement decision.” *Coyne*, 717 F. App’x at 29. Nor does it provide any “specificity” with regard to any of the particular states for which Bassan sues. *Lab. Corp. of Am.*, 2015 WL 7292774, at *6.

Finally, it is notable that every state declined to intervene in this case. (Save Indiana, which has not indicated a decision either way, despite the passage of deadlines for doing so). Although the states may have other reasons for declining to intervene, *United States ex rel. Raffington v. Bon Secours Health Sys., Inc.*, 405 F. Supp. 3d 549, 571 (S.D.N.Y. 2019), many courts find such declinations relevant where the relator has otherwise failed to allege a basis for

⁷ Bassan makes a few assertions that certain requirements are a “condition of payment” under Medicare Part D, *id.* ¶ 94, *see id.* ¶ 96, but those allegations (A) are too conclusory to plead materiality under Rules 8 and 9(b); (B) relate to the federal FCA claim only, on which the Government’s Complaint-in-Intervention is operative; and (C) are insufficient in any event because “[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment.” *Escobar*, 136 S. Ct. at 2003.

materiality, *see Cimino v. Int’l Bus. Machines Corp.*, 2019 WL 4750259, at *7 (D.D.C. Sept. 30, 2019) (decision not to intervene “is entitled to some ‘respect’” in materiality analysis, particularly where the relevant government entity declined to intervene “after a multi-year investigation” (quoting *United States ex rel. Head v. Kane Co.*, 798 F. Supp. 2d 186, 197 n.14 (D.D.C. 2011)); *United States v. Comstor Corp.*, 308 F. Supp. 3d 56, 86 (D.D.C. 2018) (“The requirement of demonstrating materiality would seem especially crucial here where the government declined to intervene after almost five years of investigation”).

III. BASSAN DOES NOT STATE A CLAIM UNDER NEW MEXICO LAW

Bassan’s claim under New Mexico law fails for all of the reasons stated above. In addition, New Mexico’s Medicaid FCA bars claims where the State has not found, in writing, substantial evidence of a violation. *See* N.M. Stat. Ann. § 27-14-7E(2). Absent such a determination—which Bassan has neither presented nor alleged here—the New Mexico Medicaid FCA claims should be dismissed. *See United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 2018 WL 6300578, at *19 (E.D. Pa. Nov. 29, 2018) (dismissing claim where the State declined to intervene and the Relator “has not obtained any written determinations of substantial evidence”), *clarified on denial of reconsideration*, 370 F. Supp. 3d 491 (E.D. Pa. 2019).

Bassan cannot evade this requirement by grounding his New Mexico claim on the general Fraud Against Taxpayers Act (“FATA”), N.M. Stat. Ann. § 44-9-1, which permits FCA actions not limited to claims involving Medicaid. Bassan’s claim is one for alleged *Medicaid* false claims, and the New Mexico Legislature enacted clear rules for such claims—including the substantial-evidence requirement—when it passed the New Mexico Medicaid FCA. The later-enacted and more general FATA should not be interpreted to repeal the requirements of the

Medicaid FCA. Indeed, “[t]he rule in New Mexico is that specific statutes control over general statutes.” *New Mexico ex rel. Rodriguez v. Am. Legion Post No. 99, Club License No. 1626*, 750 P.2d 1110, 1113 (N.M. Ct. App. 1987); *see also In re Fairfield Sentry Ltd. Litig.*, 458 B.R. 665, 680 (S.D.N.Y. 2011) (“It is a basic tenet of statutory interpretation that a statute which addresses the matter in specific terms controls over a statute which addresses the issue in general terms, unless Congress has manifested a contrary aim.” (internal quotation marks omitted)). And a “reviewing court presumes that the legislature was informed as to existing law and did not intend to enact any law inconsistent with any existing law.” *Gonzales v. Middle Rio Grande Conservancy Dist.*, 744 P.2d 554, 556 (N.M. Ct. App. 1987); *see also United States v. Jim*, 891 F.3d 1242, 1251 (11th Cir. 2018) (absent a clear intention otherwise, a specific statute “will not be controlled or nullified by a general one, regardless of the priority of the enactment”).

CONCLUSION

For the foregoing reasons, Bassan’s Complaint should be dismissed in its entirety and with prejudice.

Dated: May 4, 2020

Respectfully submitted,

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